# **Complete Summary**

#### **GUIDELINE TITLE**

Secondary prevention. In: Clinical guidelines for acute stroke management.

#### **BIBLIOGRAPHIC SOURCE(S)**

Secondary prevention. In: National Stroke Foundation. Clinical guidelines for acute stroke management. Melbourne (Australia): National Stroke Foundation; 2007 Oct. p. 43-51.

#### **GUIDELINE STATUS**

This is the current release of the guideline.

#### \*\* REGULATORY ALERT \*\*

#### FDA WARNING/REGULATORY ALERT

**Note from the National Guideline Clearinghouse (NGC)**: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

• <u>February 1, 2008, Chantix (varenicline)</u>: New information has been added to the WARNINGS and PRECAUTIONS sections in Chantix's prescribing information about serious neuropsychiatric symptoms experienced in patients taking this medication.

#### **COMPLETE SUMMARY CONTENT**

\*\* REGULATORY ALERT \*\*

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS CONTRAINDICATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

**DISCLAIMER** 

#### **SCOPE**

# **DISEASE/CONDITION(S)**

- Acute stroke (ischemia or intracerebral hemorrhage)
- Transient ischemic attack (TIA)

#### **GUIDELINE CATEGORY**

Counseling Evaluation Management Prevention Risk Assessment Treatment

#### **CLINICAL SPECIALTY**

Endocrinology
Family Practice
Geriatrics
Hematology
Internal Medicine
Neurology
Nursing
Nutrition
Physical Medicine and Rehabilitation
Preventive Medicine
Surgery

#### **INTENDED USERS**

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Health Care Providers
Health Plans
Hospitals
Nurses
Occupational Therapists
Patients
Physical Therapists
Physician Assistants
Physicians

# **GUIDELINE OBJECTIVE(S)**

- To provide evidence-based recommendations related to acute stroke care
- To help health care workers improve the quality and effectiveness of the care they provide

 To provide a logical framework from pre-hospital care through to discharge and follow up in the community

#### **TARGET POPULATION**

Adults with acute stroke or transient ischemic attack (TIA) during the early phase of care

**Note**: "Early" is defined as the first seven days of care. This guideline does NOT include recommendations on the care of those with subarachnoid hemorrhage or the care of children.

#### INTERVENTIONS AND PRACTICES CONSIDERED

# **Evaluation/Prevention/Treatment/Management**

- Smoking cessation, e.g., nicotine replacement therapy, antidepressants (bupropion, nortriptyline), nicotine receptor partial agonist therapy, behavioral therapy
- 2. Dietary changes, including limiting alcohol consumption
- 3. Increased regular exercise
- 4. Educational and motivational counseling about risk and lifestyle
- 5. Glucose tolerance testing
- 6. Blood pressure lowering treatment)
- 7. Antiplatelet therapy (aspirin, dipyridamole alone or with aspirin, clopidogrel)
- 8. Anticoagulation therapy
- 9. Cholesterol lowering therapy (statins, diet)
- 10. Diabetes management per national guidelines
- 11. Surgery
  - Carotid endarterectomy
  - Carotid angioplasty and stenting (not recommended routinely)
  - Patent foramen ovale closure (not recommended)
- 12. Timing of initiation of therapy
- 13. Adherence aids to medication regimens

#### **MAJOR OUTCOMES CONSIDERED**

- Recurrent stroke rate
- Incidence of other vascular events (e.g., myocardial infarction)
- Smoking cessation and weight loss rates
- Local and systemic complication rates
- Changes in diastolic and systolic blood pressure
- Changes in laboratory parameters (lipoprotein, triglyceride, liver enzyme levels, platelet aggregation, glomerular filtration rate, sodium excretion)
- Change in cerebral blood flow
- Rates of emboli symptoms
- Perioperative complication rates
- Rehospitalization rates
- Rate of adverse events and discontinuation medical therapy
- Percent of medication taken
- Mortality
- Cost of care

#### **METHODOLOGY**

# METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

## **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

# **Systematic Searches and Literature Review**

The systematic identification of relevant literature was conducted according to National Health and Medical Research Council (NHMRC) standards between July and November 2006. Previous international and national stroke guidelines were identified and evaluated using the AGREE tool. Guidelines developed by the Royal College of Physicians in the United Kingdom (UK) in 2004 were deemed the most recent and robust guidelines and hence were used as a basis for updating the literature searches. An external consultant was used to undertake all the electronic database searches.

#### **Question Formulation**

89 clinical questions were developed by the Expert Working Group (EWG) to address interventions relevant to acute stroke care. The questions generally queried the effects of a specific intervention and were developed in three parts: the intervention, the population and the outcomes. An example is "What is the effect of anticonvulsant therapy on reducing seizures in people with post-stroke seizures?" In this example, anticonvulsant therapy is the intervention, reduction of post-stroke seizures is the outcome, and the population is people with post-stroke seizures.

# **Finding Relevant Studies**

For this guideline searching, there could be no single search coverage for all 89 questions: some sections of the guidelines need updating only from 2003, some are topics not previously addressed in the guidelines, some have already been well researched by other reputable guidelines authorities while some have no comprehensive meta-analysis relating to them.

In order to have some structure to the searching and to make filtering of the references more manageable, the questions were searched and stored in separate Endnote libraries by broad topics:

- 1. Organisation of care
- 2. Discharge planning, transfer of care and integrated community care
- 3. Pre hospital care
- 4. Early diagnostic assessment
- 5. Management in the emergency phase
- 6. Assessment and management of consequences of stroke
- 7. Prevention and management of complications

- 8. Early secondary prevention
- 9. Palliation and death
- 10. Transient ischemic attack (TIA)

Each reference within the library was then marked with the questions for which it was relevant. For Australasian Medical Index, EMBASE, Medline and Medline inprocess & other non-indexed citations searching was conducted in four broad steps:

- a. Terms for the patient group (P) were abridged from the Cochrane Collaboration's Stroke Group.
- b. Where appropriate, intervention or other factor terms were added.
- c. Relevant evidence filters (Cochrane sensitive filter or Medline diagnostic filter) were applied to the basic search strategies.
- d. If the search was for an update only to National Stroke Foundation (NSF) or other authoritative meta-analysis, the references were limited to years 2003 onwards.

For brevity, search strategies are not included in the original guideline document but are available from the NSF. Table 3 in Appendix A of the original guideline document outlines the number of articles found for each 10 topic areas listed above.

A systematic process for choosing relevant articles occurred. At first, relevant systematic reviews were initially identified. Where no systematic review was found, primary studies were then searched. This initial process was conducted by one member of the working group. Final decision to include and review articles was made by two members of the working group after abstracts were scrutinised. Reference lists of identified articles and other guidelines were then used to identify further trials. The table of contents of a number of key journals for the last 6 months was also conducted. The following journals were chosen: Stroke, Cerebrovascular Disease, Lancet (and Lancet Neurology), and Archives of Physical Medicine and Rehabilitation. For a number of topics a general internet search was then undertaken (using the "Google" search engine). Finally, where possible, experts in the field were contacted to review the identified studies and suggest other new studies not identified. Hand searching continued until May 2007 and significant studies were included.

# **Cost Analysis**

The Guidelines project officer conducted a separate systematic review for this section. The economic literature was searched with a total of 1484 references retrieved after deduplication (see Table 4 in Appendix A of the original guideline document). One person sorted these and selected 70 potentially relevant articles. These abstracts were scrutinised for omissions by two people and appropriate papers were retrieved and reviewed (n=30).

#### NUMBER OF SOURCE DOCUMENTS

A total of 30,140 potential articles resulted from the clinical searching. After reviewing abstracts and titles, 1,411 of these were identified as being potentially useful and worth reading in more detail. Only 468 of the original were used to

write the Guidelines report and only a final 153 of the 30,140 original references were used to support the Guideline recommendations.

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

# RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

# **Designation of Levels of Evidence According to Type of Research Question**

Level	Intervention	Diagnosis	Prognosis	Aetiology	Screening
I	A systematic review of Level II studies	A systematic review of Level II studies	A systematic review of Level II studies	A systematic review of Level II studies	A systematic review of Level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among consecutive patients with a defined clinical presentation	A prospective cohort study	A prospective cohort study	A randomised controlled trial
III-1	A pseudo-randomised controlled trial (i.e., alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among consecutive patients with a defined clinical presentation	All or none	All or none	A pseudo-randomised controlled trial (i.e., alternate allocation or some other method)

Level	Intervention	Diagnosis	Prognosis	Aetiology	Screening
III-2	A comparative study with concurrent controls:  Non-randomised experimental trial Cohort study Case-control study Interrupted time series without a parallel control group	A comparison with a reference standard that does not meet the criteria required for Level II and Level III-1 evidence	Analysis of prognostic factors amongst untreated control patients in a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls:  • Nonrandomised, experimental trial • Cohort study • Case-control study
III-3	A comparative study without concurrent controls:  • Historical control study • Two or more single arm study • Interrupted time series without a parallel control group	Diagnostic case-control study	A retrospective cohort study	A case- control study	A comparative study without concurrent controls:  • Historical control study • Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)	Case series or cohort study of patients at different stages of disease	A cross- sectional study	Case series

# **METHODS USED TO ANALYZE THE EVIDENCE**

Review of Published Meta-Analyses Systematic Review with Evidence Tables

# **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

**Appraising and Selecting Studies** 

A standardised appraisal process was used based on that outlined by the Scottish Intercollegiate Guidelines Network (SIGN). Where available, appraisals already undertaken by the Stroke Therapy Evaluation Program (STEP) team were used to avoid duplication. The standardised appraisal form assesses the level of evidence (design and issues of quality), size of effect, relevance, applicability (benefits/harms) and generalisability of studies. Examples of completed checklists can be found on the STEP website (<a href="https://www.effectivestrokecare.org">www.effectivestrokecare.org</a>). Where Level I or II evidence was unavailable the search was broadened to include lower levels of evidence. Evidence for diagnostic and prognostic studies was also appraised using the SIGN methodology.

#### **Summarising and Synthesising the Evidence**

Details of relevant studies were summarised in evidence tables which form a supplement to this document. The supplement is available for download from the National Stroke Foundation (NSF) website (<a href="www.strokefoundation.com.au">www.strokefoundation.com.au</a>).

For each question the evidence was collated using the draft National Health and Medical Research Council (NHMRC) "Assessing the body of evidence form". The recommended grading matrix was used to guide the strength or grading of the recommendation. For each question, the working group discussed and agreed on draft recommendations. The body of evidence matrix along with the draft recommendation gradings are shown in the original guideline document.

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Clinical Guidelines for Acute Stroke Management have been developed according to processes prescribed by the National Health and Medical Research Council (NHMRC) under the direction of an interdisciplinary Expert Working Group (EWG) (see Appendix A in the original guideline document). The draft 'Additional levels of evidence and grades for recommendations for developers of guidelines pilot program 2005-2007' has been used to assist in grading the recommendations along with specifying levels of evidence. Consultation from other individuals and organisations was also included in the development process in line with NHMRC standards. Details about the development methodology and consultation process are outlined in Appendix A in the original guideline document.

A consumer was included in the EWG and has been involved in every phase of the development process, including the development of the clinical questions to guide the literature searching. In addition a number of consumer organisations were specifically sent the draft document and asked to provide any comments reflecting the views of consumers. Finally a two part structured consultation process was also undertaken by an independent team from the University of Queensland on behalf of the National Stroke Foundation to understand the views of consumers on the current document. The first phase discovered the views of consumers on the best process to engage consumers and receive feedback on the guidelines. Based

on the results of this qualitative data, consumers from a wide range of locations, stroke severities, carer/survivor mix, and other demographics were collected. For details of the results of this consultation see Appendix A in the original guideline document. In addition, the process of developing the Clinical Guidelines for Acute Stroke Management has importantly included input and advice from stroke survivors and their family/carer.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

#### **Grading of Recommendations**

Grade	Description			
A	Body of evidence can be trusted to guide practice			
В	Body of evidence can be trusted to guide practice in most situations			
С	Body of evidence provides some support for recommendation(s) but care should be taken in its application			
D	Body of evidence is weak and recommendation must be applied with caution			
Clinical Practice Points				
СРР	Recommended best practice based on clinical experience and expert opinion			

#### **COST ANALYSIS**

There is good evidence of cost-effectiveness for the most clinically effective and important stroke prevention and treatment strategies recommended in this guideline. In particular, the findings from a recent modelling exercise in the Australian setting indicate that more widely accessible, evidence-based stroke care could produce substantial economic and health-related benefits and would require only modest investment. The authors suggested that if there was improved access of eligible stroke patients to effective acute care (stroke units and intravenous thrombolysis) and secondary prevention (blood pressure [BP] lowering, warfarin for atrial fibrillation [AF], aspirin in ischaemic stroke and carotid endarterectomy), as well as improved management of BP and AF as primary prevention in the Australian population, then about \$1.06 billion could be recovered as potential cost offsets with recovery of more than 85,000 disability adjusted life years (DALYs). Therefore, clinical guidelines such as these which promote improved treatment and prevention of stroke are an important contribution to achieving such increased access and the cost-effective use of health resources in this country.

See Section 9 titled *Cost and Socioeconomic Implications* in the original guideline document presents for details of the review of the cost and socioeconomic implications of providing evidence based stroke care supported by the recommendations contained within this guideline.

#### METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

#### **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Public consultation was undertaken, with the draft document circulated to relevant professional bodies, interested individuals, consumers and consumer organisations over one month from mid April to the third week in May 2007. A public notice was also published in *The Australian* (April 19, 2007). Feedback received during consultation was considered by the Expert Working Group (EWG) and the draft document amended. A formal letter of reply was sent to all individuals and organisations that provided feedback during this period outlining the response taken by the EWG.

In response to the major issues received during consultation an independent expert was asked to review the key studies for the topic in question, in addition to other selected topics, and to advise the working group if the EWG had accurately interpreted and applied the evidence. Independent appraisals of the key studies along with an overall judgement about the appropriateness of the interpretation were provided. Only one recommendation was significantly changed based on this review with the vast majority of recommendations deemed to be in line with the evidence base. Further details are available in Appendix A of the original guideline document.

Several prompted questions were also asked and the response noted in Table 5 in Appendix A of the original guideline document.

#### **RECOMMENDATIONS**

#### **MAJOR RECOMMENDATIONS**

The levels of evidence supporting the recommendations (I-IV) and grades of recommendations (A-D and clinical practice points [CPP]) are defined at the end of the "Major Recommendations" field.

The original guideline document also includes a consumer rating that identifies aspects of care considered to be critical from a patient perspective.

#### **Behaviour Change**

Every person with stroke should be assessed and informed of their risk factors for a further stroke and possible strategies to modify identified risk factors. The risk factors and interventions include:

- Smoking cessation: nicotine replacement therapy, bupropion or nortriptyline therapy, nicotine receptor partial agonist therapy and/or behavioural therapy should be considered; (Grade A; Level I [Silagy et al., 2004; Hughes, Stead, & Lancaster, 2007; Cahill, Stead, & Lancaster, 2007; Sinclair, Bond, & Stead, 2004; Rice & Stead, 2004; Lancaster & Stead, 2005; Stead, Perera, & Lancaster, 2006])
- Improving diet: a diet that is low in fat (especially saturated fat) and sodium, but high in fruit and vegetables should be consumed; (Grade A; Level I [He & MacGregor, 2004; Hooper et al., 2004; Jurgens & Graudal, 2004; He,

- Nowson, & MacGregor, 2006; Hooper, et al., 2001] **& Level II** [Sacks et al., 2001; Appel et al., 1997; Barzi et al., 2003; de Lorgeril et al., 1999])
- Increasing regular exercise; (Grade C; metaanalysis of cohort studies in primary prevention demonstrate strong link between low exercise and stroke risk [Lee, Folsom, & Blair, 2003; Wendel-Vos et al., 2004; Oguma & Shinoda-Tagawa, 2004])
- Avoiding excessive alcohol. (Grade C; metaanalysis of cohort studies in primary prevention demonstrate link between high alcohol intake and stroke risk [Reynolds et al., 2003])

Interventions should be individualised and may be delivered using behavioural techniques (such as educational or motivational counselling). (**Grade A; Level I** [Stead & Lancaster, 2005; Sinclair, Bond, & Stead, 2004; Rice & Stead, 2004; Lancaster & Stead, 2005; Stead, Perera, & Lancaster, 2006; Rubak et al., 2005; Pignone & Mulrow, 2001)

#### **Blood Pressure Lowering**

All patients after stroke or transient ischaemic attack (TIA), whether normotensive or hypertensive, should receive blood pressure lowering therapy, unless contraindicated by symptomatic hypotension. (**Grade A; Level I** [Rashid, Leonardi-Bee, & Bath, 2003])

Commencement of new blood pressure lowering therapy may occur prior to discharge or within the first week after stroke or TIA. (**Grade B; Level II** [Nazir et al., 2004; Nazir et al., 2005] **& Level III-3** [Ovbiagele et al., 2004])

#### **Antiplatelet Therapy**

Long term antiplatelet therapy should be prescribed to all people with ischaemic stroke or TIA who are not prescribed anticoagulation therapy. (**Grade A; Level I** [Antithrombotic Trialists Collaboration, 2003])

Low dose aspirin and modified release dipyridamole should be prescribed to all people with ischaemic stroke or TIA who do not have concomitant acute coronary disease. (**CPP** [ESPRIT Study Group et al., 2006; Diener et al., 1996])

Aspirin alone or clopidogrel alone may be used for people who do not tolerate aspirin plus dipyridamole therapy. Clopidogrel alone should be used for those who are intolerant of aspirin or in whom aspirin is contraindicated. (**CPP** [Antithrombotic Trialists Collaboration, 2003])

The combination of aspirin plus clopidogrel is not recommended in the secondary prevention of cerebrovascular disease in patients who do not have acute coronary disease or recent coronary stent. (**Grade A; Level II** [Diener et al., 2004; Bhatt et al., 2006])

#### Anticoagulation Therapy

Anticoagulation therapy for long-term secondary prevention should be used in all people with ischaemic stroke or TIA who have atrial fibrillation, cardioembolic

stroke from valvular heart disease, or recent myocardial infarction, unless a contraindication exists. (**Grade A; Level I** [Saxena & Koudstaal, "Anticoagulants for preventing stroke," 2004; Saxena & Koudstaal, "Anticoagulants versus antiplatelet therapy," 2004])

Anticoagulation therapy for secondary prevention for those people with ischaemic stroke or TIA from presumed arterial origin should not be routinely used as there is no evidence of additional benefits over antiplatelet therapy. (**Grade A; Level I** [Algra et al., 2006])

The decision to commence anticoagulation therapy should be made prior to discharge. (**Grade C; Level III-3** [Ovbiagele et al., 2004])

In patients with TIA, commencement of anticoagulation therapy should occur once CT or MRI has excluded intracranial haemorrhage as the cause of the current event. (**CPP**)

# **Cholesterol Lowering**

Therapy with a statin should be used for all patients with ischaemic stroke or TIA. (**Grade B; Level II** [Collins et al., 2004; Amarenco et al., 2006])

Patients with high cholesterol levels should receive dietary review and counselling by a specialist, trained clinician. (**Grade B; Level I** [Ruback et al., 2005; Pignone & Mulrow, 2001])

## **Diabetes Management**

All acute stroke patients should have their glucose monitored. Patients with glucose intolerance or diabetes should be managed in line with national guidelines for diabetes. (**CPP**)

## **Carotid Surgery**

Carotid endarterectomy should be undertaken in patients with nondisabling carotid artery territory ischaemic stroke or TIA with ipsilateral carotid stenosis measured at 70-99% (North American Symptomatic Carotid Endarterectomy Trial [NASCET] criteria) if surgery can be performed by a specialist surgeon with low rates of perioperative mortality/morbidity. (**Grade A; Level I** [Cina, Clase, & Haynes, 1999; Rothwell et al., 2003])

Carotid endarterectomy should be undertaken in select patients (considering age, gender and comorbidities) with nondisabling carotid artery territory ischaemic stroke or TIA with ipsilateral carotid stenosis measured at 50-69% (NASCET criteria) if surgery can be performed by a specialist surgeon with very low rates of perioperative mortality/morbidity. (**Grade A; Level I** [Cina, Clase, & Haynes, 1999; Rothwell et al., 2003])

Carotid endarterectomy may be undertaken in highly select patients (considering age, gender and comorbidities) with asymptomatic carotid stenosis of 60-99% if it can be performed by a specialist surgeon with very low rates of perioperative

mortality/morbidity. (**Grade A; Level I** [Cina, Clase, & Haynes, 1999; Rothwell et al., 2003])

Eligible patients should undergo carotid endarterectomy as soon as possible after the event (ideally within 2 weeks). (**Grade A; Level I** [Rothwell et al., 2004])

Carotid endarterectomy should only be performed by a specialist surgeon at centres where outcomes of carotid surgery are routinely audited. (**Grade B; Level I** [Cina, Clase, & Haynes, 1999])

Carotid endarterectomy is not recommended for those with <50% symptomatic stenosis or those with <60% asymptomatic stenosis. (**Grade A; Level I** [Cina, Clase, & Haynes, 1999; Chambers, 2005])

Carotid angioplasty and stenting should not routinely be considered for patients with symptomatic stenosis. However, it may be considered as an alternative in certain circumstances, that is in patients who meet criteria for carotid endarterectomy but are deemed unfit due to medical comorbidities (e.g., significant heart/lung disease, age >80 yrs), or conditions that make them unfit for open surgery (e.g., high or low carotid bifurcation, carotid re-stenosis). (**Grade B; Level I** [Coward, Featherstone, & Brown, 2004] **& Level II** [SPACE Collaborative Group, 2006; Mas et al., 2006])

#### **Patent Foramen Ovale (PFO)**

All patients with an ischaemic stroke or TIA, and a PFO, should receive antiplatelet therapy as first choice. (**Grade C; Level II** [Homma et al., 2002])

Anticoagulation may also be considered taking into account other risk factors and the increased risk of harm. (**Grade C; Level II** [Homma et al., 2002])

Currently there is insufficient evidence to recommend PFO closure. (CPP)

#### **Concordance with Medication**

Interventions to promote adherence to medication regimes are often complex and should include one or more of the following:

- Information, reminders, self-monitoring, reinforcement, counselling, family therapy. (Grade B; Level I [Schroeder, Fahey, & Ebrahim, 2004; Schedlbauer et al., 2004; Haynes et al., 2005])
- Reduction in the number of daily doses. (Grade B; Level I [Schroeder, Fahey, & Ebrahim, 2004; Schedlbauer et al., 2004])
- Multi-compartment medication compliance device. (Grade C; Level I [McGraw, 2004; Heneghan, Glasziou, & Perera, 2006])

#### **Definitions:**

#### **Levels of Evidence**

Level	Intervention	Diagnosis	Prognosis	Aetiology	Screening
I	A systematic review of Level II studies	A systematic review of Level II studies	A systematic review of Level II studies	A systematic review of Level II studies	A systematic review of Level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among consecutive patients with a defined clinical presentation	A prospective cohort study	A prospective cohort study	A randomised controlled trial
III-1	A pseudo-randomised controlled trial (i.e., alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among consecutive patients with a defined clinical presentation	All or none	All or none	A pseudo-randomised controlled trial (i.e., alternate allocation or some other method)
III-2	A comparative study with concurrent controls:  Non-randomised experimental trial Cohort study Case-control study Interrupted time series	A comparison with a reference standard that does not meet the criteria required for Level II and Level III-1 evidence	Analysis of prognostic factors amongst untreated control patients in a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls:  • Nonrandomised, experimental trial • Cohort study • Case-control study

Level	Intervention	Diagnosis	Prognosis	Aetiology	Screening
	without a parallel control group				
III-3	A comparative study without concurrent controls:  • Historical control study • Two or more single arm study • Interrupted time series without a parallel control group	Diagnostic case-control study	A retrospective cohort study	A case- control study	A comparative study without concurrent controls:  • Historical control study • Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)	Case series or cohort study of patients at different stages of disease	A cross- sectional study	Case series

# **Grading of Recommendations**

Grade	Description			
A	Body of evidence can be trusted to guide practice			
В	Body of evidence can be trusted to guide practice in most situations			
С	Body of evidence provides some support for recommendation(s) but care should be taken in its application			
D	Body of evidence is weak and recommendation must be applied with caution			
Clinical Practice Points				
СРР	Recommended best practice based on clinical experience and expert opinion			

# **CLINICAL ALGORITHM(S)**

None provided

# **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

#### BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### **POTENTIAL BENEFITS**

- Reduction in the recurrence of stroke and combined vascular events including myocardial infarction
- Reduction in mortality

#### **POTENTIAL HARMS**

- Antiplatelet therapy may have adverse effects, particularly a small risk of hemorrhage, but the benefits outweigh the risks.
- The main adverse effect of combination therapy with extended release dipyridamole plus aspirin is headache (34% ceased medication compared with 17% for aspirin alone over 5 years).
- Carotid artery surgery is not without risks that need to be considered and discussed with the patient and their family/carer. For example, gender, age and comorbidity should be carefully considered in patients with symptomatic stenosis between 50% and 69%, as the absolute benefit of surgery is less than that for more severe degrees of stenosis.
- Warfarin used for medical management of patent foramen ovale was found to have higher rates of minor bleeding compared with aspirin.

#### **CONTRAINDICATIONS**

#### **CONTRAINDICATIONS**

Blood pressure lowering therapy is contraindicated in patients with symptomatic hypotension.

#### **QUALIFYING STATEMENTS**

#### **QUALIFYING STATEMENTS**

 This document is a general guide to appropriate practice, to be followed subject to the clinician's judgement and the patient's preference in each individual case. The guidelines are designed to provide information to assist

- decision-making and are based on the best evidence available at the time of development.
- The guidelines should not be seen as an inflexible recipe for stroke care; rather, they provide a framework that is based on the best available evidence that can be adapted to local needs, resources and individual circumstances.

#### IMPLEMENTATION OF THE GUIDELINE

#### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

Reviewing the evidence and developing evidence-based recommendations for care involves only the first steps to ensuring that evidence-based care is available. Following publication of the Clinical Guidelines for Acute Stroke Management, the guidelines must be disseminated to all those who provide care of relevance to acute stroke care, who may then identify ways in which the guidelines may be taken up at a local level.

Strategies by which guidelines may be disseminated and implemented include:

- Distribution of education materials for example: mailing of guidelines to stroke clinicians via existing stroke networks will be undertaken. Concise guidelines (in particular for General Practitioners [GPs]) are also planned with GP networks utilised to circulate this new information. Guidelines documents will also be sent to all appropriate universities, colleges, associations, societies and other professional organisations.
- Educational meetings for example: interdisciplinary conferences or internet based 'web conferences' are planned. Resources will be developed to aid workshop facilitators identify barriers and solutions in the implementation phase.
- Educational outreach visits A peer support model using sites viewed as 'champions' in aspects of acute stroke management may be used in collaboration with national audit results.
- Local opinion leaders Educational resources will utilise key opinion leaders.
   It is also planned to have local champions facilitate workshops in their local areas.
- Audit and feedback Data from the first national audit of acute stroke will be fundamental to the implementation of these guidelines. A copy of relevant indicators covering organisation of care and clinical care will be available from the National Stroke Foundation (NSF) along with key reports.
- Reminders Electronic reminders will be used once local teams have identified key areas of improvement and commenced planned strategies.

A systematic review of the above dissemination and implementation strategies found that there was difficulty in interpreting the evidence of the effectiveness of these interventions due to methodological weaknesses, poor reporting of the study setting and uncertainty about the generalisability of the results. However, most of the strategies appear to have modest effectiveness in implementing evidence based care, but it is unclear if single interventions are any better or worse than multiple interventions. Thus, all of the above strategies may be used where appropriate for implementation of the Clinical Guidelines for Acute Stroke Management. Specific strategies will also be considered when targeting general

practice in line with the Royal Australian College of General Practitioners (RACGP) Guidelines for "Putting prevention into practice". Implementation of these stroke Guidelines may also be supported by existing resources and networks. These include:

- The Stroke Services in Australia report, which outlines how stroke services may be organised in different parts of Australia and the resources that may be needed to do this (available at <a href="https://www.strokefoundation.com.au">www.strokefoundation.com.au</a>).
- The Stroke Care Pathway, which provides a checklist addressing key processes of care as outlined in both documents (Acute, and Rehabilitation and Recovery) and a guide to developing local protocols (available from www.strokefoundation.com.au or www.health.gov.au).
- Other specific workshop resources to aid implementation (e.g., CD Rom or self directed workbook).
- Various networks including Stroke Services New South Wales (NSW),
   Queensland (QLD) Stroke collaborative and other state and local networks.

In considering implementation of these Guidelines at a local level, health professionals are encouraged to identify the barriers and facilitators to evidence-based care within their environment to determine the best strategy for local needs.

#### **Consumer Versions of the Clinical Guidelines**

Consumer versions of the Clinical Guidelines for Acute Stroke Management and Clinical Guidelines for Stroke Rehabilitation and Recovery documents have been developed through partnerships between the National Stroke Foundation and State Stroke Associations throughout Australia. Given the different needs of stroke survivors and their families at different stages of recovery, the two Clinical Guideline documents are presented as three books for consumers. These books are available through the National Stroke Foundation and State Stroke Associations.

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

#### **IMPLEMENTATION TOOLS**

Patient Resources Quick Reference Guides/Physician Guides

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

#### **IOM CARE NEED**

Getting Better Living with Illness Staying Healthy

#### **IOM DOMAIN**

Effectiveness
Patient-centeredness

#### **IDENTIFYING INFORMATION AND AVAILABILITY**

# **BIBLIOGRAPHIC SOURCE(S)**

Secondary prevention. In: National Stroke Foundation. Clinical guidelines for acute stroke management. Melbourne (Australia): National Stroke Foundation; 2007 Oct. p. 43-51.

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

#### **DATE RELEASED**

2007 Oct

#### **GUIDELINE DEVELOPER(S)**

National Stroke Foundation (Australia) - Private Nonprofit Organization

#### **SOURCE(S) OF FUNDING**

Australian Government Department of Health and Ageing

## **GUIDELINE COMMITTEE**

**Expert Working Group** 

#### **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

Group Members: Dr Alan Barber, Neurologist, Auckland City Hospital; Dr Christopher Beer, Senior Lecturer, University of Western Australia and Geriatrician/Clinical Pharmacologist Royal Perth and Mercy Hospitals and Swan Health Service; Prof Justin Beilby, Executive Dean, Faculty of Health Sciences and Professor of General Practice, University of Adelaide; Assoc Prof Julie Bernhardt, Physiotherapist, National Stroke Research Institute; Prof Christopher Bladin, Neurologist, Box Hill Hospital; Ms Brenda Booth, Consumer, Working Aged Group with Stroke, NSW; Dr Julie Cichero, Speech Pathologist, Private Practice & University of Queensland; Ms Louise Corben, Occupational Therapy, Monash Medical Centre & Bruce Lefroy Centre Murdoch Children's Research Institute; Dr Denis Crimmins (Chair) Neurologist, Gosford Hospital; Dr Richard Gerraty,

Neurologist, Alfred Hospital and Monash University; Mr Kelvin Hill, Manager, Guidelines Program, National Stroke Foundation; Dr Erin Lalor, Chief Executive Officer, National Stroke Foundation; Assoc Prof Christopher Levi, Neurologist, John Hunter Hospital; Prof Richard Lindley, Professor of Geriatric Medicine, University of Sydney and Westmead Hospital; Prof Sandy Middleton, School of Nursing (NSW & ACT), Australian Catholic University; Ms Fiona Simpson, Dietitian and Senior Research Fellow, Royal North Shore Hospital Sydney

#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the working group completed and signed a declaration of potential conflicts of interest with development of these guidelines. Most had no perceived conflicts. The reasons provided for potential conflicts primarily involved receiving money from non commercial and commercial organisations specifically for undertaking clinical research. This was expected given the expertise of members of the working group in clinical research. Only a small number of members had received financial support from commercial companies for providing consultancy or lecturing.

# **ENDORSER(S)**

Australian and New Zealand Society for Geriatric Medicine - Medical Specialty Society

Australian College of Rural and Remote Medicine - Professional Association Australian Physiotherapy Association - Medical Specialty Society BeyondBlue: The National Depression Initiative - National Government Agency [Non-U.S.]

Council of Ambulance Authorities (Australia) - Professional Association Dietitians Association of Australia - Professional Association Occupational Therapy Australia - Professional Association Royal Australian and New Zealand College of Radiologists - Professional Association

Speech Pathology Australia - Medical Specialty Society Stroke Society of Australasia - Disease Specific Society

# **GUIDELINE STATUS**

This is the current release of the guideline.

#### **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the <u>National</u> Stroke Foundation (Australia) Web site.

Print copies: Available from the National Stroke Foundation (Australia), Level 7, 461 Bourke Street, Melbourne Victoria 3000, Australia.

#### **AVAILABILITY OF COMPANION DOCUMENTS**

The following is available:

 Clinical guidelines for acute stroke management – supplement. Melbourne (Australia): National Stroke Foundation; 2007 Oct. 67 p. Electronic copies: Available in Portable Document Format (PDF) from the <u>National Stroke</u> Foundation (Australia) Web site.

#### **PATIENT RESOURCES**

The following are available:

- Early testing and treatment. Melbourne (Australia): National Stroke Foundation: 2005. 16 p.
- Stroke rehabilitation. Melbourne (Australia): National Stroke Foundation;
   2005. 19 p.
- Long term recovery. Melbourne (Australia): National Stroke Foundation; 2005. 16 p.

Electronic copies: Available in Portable Document Format (PDF) from the <u>National Stroke Foundation (Australia) Web site</u>.

Print copies: Available from the National Stroke Foundation (Australia), Level 7, 461 Bourke Street, Melbourne Victoria 3000, Australia.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

#### **NGC STATUS**

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